DETAILED ACTION

1. Claims 1-14, 16-32, 34-37, 47-49 and 51-60 are allowable. Claims 18, 25, 26, 28-31, and 49, previously withdrawn from consideration as a result of a restriction requirement, require all the limitations of an allowable claim. Pursuant to the procedures set forth in MPEP § 821.04(a), **the restriction requirement between Species I and II, as set forth in the Office action mailed on 17 May 2007, is hereby withdrawn** and claims 18, 25, 26, 28-31, and 49 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. In view of the withdrawal of the restriction requirement, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Charles Schmal on 22 January 2008.

The application has been amended as follows:

At claim 32, line 4, "the housing proximal" has been deleted.

At claim 49, line 2 --includes-- has been inserted before "at least a pair".

In the specification, at page 10, line 9, through page 11, line 14:

"In a further embodiment, the lancet is slidably received inside the capillary channel. The lancet in this embodiment is generally flat. By being positioned inside the channel, the lancet is supported and stabilized by the housing throughout the entire lancing stroke so that the lancet remains in proper alignment during lancing. The support provided by the housing around the lancet prevents the lancet from laterally deflecting or bending during lancing, which in turn prevents the incision from being formed at the wrong location or angle. As will be appreciated from the discussion below, this design also allows the flat lancet to be formed from thinner material than previously possible, which in turn ~~may reduce~~ may reduce the pain associated with lancing. Moreover, this configuration ensures that the capillary channel is positioned directly over the incision. The device further includes a retraction mechanism for retracting the lancet into the housing after lancing the skin. During lancing, the lancet extends from the opening of the capillary channel so as to form an incision in the skin. In one form, the device has a skin contacting edge positioned next to the opening of the capillary channel in order to provide a reference surface for flattening the skin around the lancet.

By flattening the skin around the lancet, an incision with a precise depth can be formed. In a further ~~from~~ form, the device incorporates an adjustment mechanism for adjusting the penetration depth of the lancet. Once the skin has been lanced, the retraction mechanism withdraws the lancet back into the housing. The bodily fluid from the incision is then drawn into the channel and around the lancet via capillary action. As should be appreciated, by having the lancet positioned within the capillary channel, the opening of the capillary channel is positioned over the incision ~~cite~~ site before lancing. This eliminates the need to reposition the capillary over the incision subsequent to lancing the incision. After the fluid has been drawn within the capillary channel, the fluid is then transported to a means for testing the fluid, such as a test strip.

As will be appreciated from the discussion below, the number of steps involved in obtaining a sample is significantly reduced using the integrated device according to the present invention. The capillary channel in the integrated device does not have to be repositioned over the incision after lancing. Consequently, the difficulties associated with moving a capillary tube quickly and accurately to the incision site ~~is~~ are significantly reduced. It therefore enhances the ability to acquire the expressed body fluid without loss, delay or contamination. Moreover, the devices according to the present invention are useful for sampling and analyzing various type bodily fluids. For example, the devices can be suitable for sampling either blood or interstitial fluid."

3. The following is an examiner's statement of reasons for allowance: claim 1 line 13 "the sampling end portion of the flexible sheet being at least as long as the lancet

tip"; claim 32 lines 8 and 10 "bending the flexible sheet against the skin during said lancing; … straightening the flexible sheet during said retracting"; claim 47 line 11 "the sheet extending past the lancet tip for drawing the bodily fluid into the channel"; claim 57 lines 8-9 "the sampling end portion of the fluid collection sheet being at least as long as the lancet tip"; and claim 59 line 5 "bending the fluid collection sheet against the skin during said cutting the incision", when considered with the other limitations of each respective claim, are not found in the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily M. Lloyd whose telephone number is 571-272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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